ABBOTT

Corporate Regulatory Affairs

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May 24, 1999

The Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20857

RE: Draft Guidance for Industry: Accelerated Approval Products--Submission of Promotional Materials [Docket No. 99D-0484]

Dear Sir or Madam:

Abbott Laboratories submits the following remarks in response to the Agency's request for comments on the above-named subject and docket. Abbott is an integrated worldwide manufacturer of healthcare products employing more than 56,000 people and serving customers in more than 130 countries.

Section II. Background (page 1)
Draft Verbiage: "The regulations require further that promotional materials intended for dissemination any time after the 120-day postapproval period be submitted at least 30 days prior to the intended date of initial dissemination or publication of those materials, unless otherwise informed by the Agency."

Response: Press materials, particularly press releases, are time-sensitive. Press materials are created in response to a changing communications environment or newly available information. The planning period that may be utilized for sales aids and other types of promotional materials frequently does not exist when press materials are created. Under usual business practices, press materials may be created and "published" in a matter of days.

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However, press materials that pertain to an accelerated approval product can be delayed for up to 30 days while the pre-clearance requirement is met.

We interpret the phrase "...unless otherwise informed by the Agency" to mean that the Agency has discretionary authority over the length of time required for review and release of materials. In consideration of the need for timeliness with respect to press materials, we suggest that the Agency establish in the referenced guidance that press materials need to be submitted for review at least seven days rather than 30 days prior to publication.

Finally, we believe that the Agency should discuss this guideline and any progress that may have occurred as a result of the public comment period at one or more open meetings with industry. Communication and regular updates of this type will further the understanding of all parties involved.

Yours truly,

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